UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA	)	
v.	)	
	)	No. 23-cr-69-TSM-01/02
CENTERA BIOSCIENCE, d/b/a NOOTROPICS DEPOT, and PAUL EFTANG,	)	
Defendants	)	

GOVERNMENT'S SENTENCING MEMORANDUM

The defendants violated the Federal Food, Drug, and Cosmetic Act (FDCA) by selling unapproved prescription drugs to consumers without a valid prescription or adequate instructions for use. This type of conduct has the potential to cause serious harm to individuals. However, the defendants have agreed to swiftly take responsibility for their conduct, forfeit all drugs seized by law enforcement, and pay a $2.4 million forfeiture. In addition, after this investigation became overt the defendants immediately ceased their illegal activity. Accordingly, and for the following reasons, the Government requests the Court adopt the stipulated Guidelines sentences.

I. Factual Background

Nootropics Depot LLC is a subsidiary of the corporate defendant, Centera Bioscience. PSR ¶ 7.[1] The company itself is physically based in Tempe, Arizona. PSR ¶ 7. The individual defendant, Paul Eftang, is the company's President and CEO. PSR ¶ 7. Eftang's mother and half-brother serve as the company General Manager and Finance Director, respectively. PSR ¶ 7. Paul Sheard serves as the company's "Strategic Director." PSR ¶ 7.

[1] Unless otherwise specified, all cites to the presentence investigation report (PSR) are to the corporate PSR.

As relevant here, the FDCA defines "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), and "articles . . . intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C). A prescription drug includes any drug which, because of its toxicity or other potential for harmful effect, is not for use except under the supervision of a practitioner licensed to administer prescription drugs. 21 U.S.C. § 353(b)(1)(A). In addition, under the FDCA drugs must be properly labeled. PSR ¶¶ 9-10. A drug is misbranded under the FDCA if its labeling fails to bear "adequate directions for use." 21 U.S.C. § 352(f)(1). In turn, adequate directions entail instructions under which laypersons can use a drug safely, and include such things as instructions concerning the quantity and frequency of dosage for each intended use. 21 C.F.R. § 201.5. A prescription drug is also misbranded under the FDCA if it is dispensed without a lawful prescription. 21 U.S.C. § 353(b)(1).

Law enforcement learned that Nootropics Depot was selling various prescription drugs, including racetams, phenibut, adrafinil, and tianeptine (together, the "Unapproved Drugs"), to consumers. PSR ¶ 12. Racetams include piracetam, aniracetam, coluracetam, and phenylpiracetam. PSR ¶ 12. The FDA has not approved any of these drugs for use in the United States and warned that tianeptine in particular has serious side effects and a high risk of addiction. PSR ¶ 13.

Generally, the company would import the raw material for the Unapproved Drugs from China. For example, during the course of this investigation Customs and Border Protection detained several shipments of adrafinil and racetams addressed to Centera Bioscience or a Centera subsidiary, Supplement Logistics. PSR ¶ 20. These shipments included 20 barrels of phenibut hydrocholoride from Shanghai Norky Pharmaceutical, 40 barrels of piracetam from

Shanghai Soyoung Biotechnology, and 20 barrels of phenibut hydrochloride from Qingdao Sincess. PSR ¶¶ 21-23. The company's Strategic Director, Paul Sheard, falsely represented to Customs that these drugs were only to be "used in laboratory analysis, research and development" and were "not for consumption or for diagnostic, therapeutic, or other household uses." PSR ¶ 20. The customs paperwork also incorrectly labeled the imports as Aromatic Monoamine or Lactoms:N-Vinyl2-Pyrrolidone. PSR ¶¶ 21-23.

Nootropics Depot maintained an active online presence to advertise the Unapproved Drugs. As of August 2021, it had paid over $4 million to advertise the Unapproved Drugs on websites such as Facebook and Google. PSR ¶ 14. As a result, searches for terms like "nootropics," "phenibut," and "piracetam" returned Nootropics Depot as the top search result on Google. PSR ¶ 14. The company also had a sub-forum on the website Reddit.com. PSR ¶ 15. On this forum, company customers would discuss various products, including the Unapproved Drugs, and company employees responded to inquiries. PSR ¶ 15. Eftang himself posted regularly on the forum under the username "MisterYouAreSoDumb." PSR ¶ 15.

The company sold its products across the United States, including in New Hampshire. At one point, the company also used Mexican intermediaries to ship products to customers. PSR ¶¶ 16-19. During the course of the investigation, undercover FDA agents purchased Unapproved Drugs from Nootropics Depot's website, including phenibut, tianeptine, and racetams. PSR ¶¶ 25-39. The products were shipped from the company's headquarters in Arizona, and did not bear any directions for use, such as dosage or intended use. PSR ¶ 40. The company also never requested a prescription to sell the drugs. PSR ¶ 41. The labels though did acknowledge that the products were not approved by the FDA. PSR ¶ 40.

In December 2021, law enforcement executed search warrants at the company's

headquarters and offices and Arizona. PSR ¶ 46. Agents seized large quantities of the Unapproved Drugs, which are being forfeited as part of this case. PSR ¶ 46.

An analysis of import and company bank records indicates that between April 10, 2017 and September 30, 2021, Centera Bioscience and Eftang purchased over $7.4 million worth of product from known suppliers of the raw material for the Unapproved Drugs. PSR ¶ 42. Again, the primary source of the Unapproved Drugs was China. PSR ¶ 42. The majority of payments, approximately $4.2 million, were made to Qingdao Sincess. PSR ¶ 42. An FDA forensic analyst estimated that the total revenues the defendants earned from selling these drugs was $35 million. PSR ¶ 45.

II. Guidelines Applicability

The parties agree with Probation's determination that because Centera Bioscience is an organizational defendant, there is no Guideline imprisonment range. Rather, the maximum sentence for that defendant is a term of probation of five years. PSR ¶ 62.

The parties also agree that because the offense did not involve fraud, the total offense level for defendant Eftang is 2. Eftang PSR ¶ 59. That, coupled with his lack of criminal history, yields a Guidelines range of 0-6 months in Zone A of the sentencing table. Eftang PSR ¶ 89.

III. Argument

Because the stipulated sentences are within the Guidelines, no departure or variance is necessary. Nonetheless, the sentencing statute, 18 U.S.C. § 3553, sets forth the factors district courts must consider in imposing a just sentence. Those factors include "the nature and circumstances of the offense," "the history and characteristics of the defendant," and the "need for the sentence imposed to reflect the seriousness of the offense, to promote respect for the

law," and "to afford adequate deterrence to criminal conduct." 18 U.S.C. § 3553(a)(1) & (2). These factors weigh in favor of the proposed sentences.

On one hand, although the defendants pled guilty to a misdemeanor, they committed a serious crime. As set forth in the plea agreement and PSR, they imported millions of dollars' worth of Unapproved Drugs from China and provided incorrect information to Customs. They ultimately sold the Unapproved Drugs to consumers nationwide without adequate directions for use or requiring a prescription, despite the potential harm the drugs pose. The FDA has warned that those drugs are unsafe and can cause serious harm to consumers if ingested. This goes to the heart of the FDCA.

Nevertheless, the Government agrees that the defendants did not act with fraudulent intent. This is reflected by the Sentencing Guidelines, which call for a probationary sentence. For example, the defendants did not attempt to trick or deceive any consumers in its marketing. The Unapproved Drugs also constituted only a portion of the defendants' business activity, and Centera Bioscience continues to sell lawful products to this day. Perhaps most importantly, the defendants took remedial steps after this investigation became overt. As noted in the PSR, the defendants retained counsel to ensure compliance with the FDCA, and ceased selling the Unapproved Drugs. PSR ¶ 58. These considerations, coupled with the defendants' swift willingness to accept responsibility and pay $2.4 million, weigh strongly in favor of the proposed sentences.

IV. Conclusion

For the foregoing reasons, the Government respectfully requests the Court impose the parties' stipulated sentences.

Respectfully submitted,

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United States Attorney

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By: /s/ Alexander S. Chen

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